919. Adulteration and misbranding of Hain Abgede Capsules. U. S. v. Harold Hain (Hain Pure Food Co.) Plea of not guilty. Tried to the court. Judgment of guilty. Fine, $200, $100 of which was suspended. (F. D. C. No. 4154. Sample No. 32640–E.)

On September 10, 1941, the United States attorney for the Southern District of California filed an information against Harold Hain, trading as the Hain Pure Food Co., Los Angeles, Calif., alleging shipment on or about October 11, 1940, from the State of California into the State of Arizona of a quantity of Hain Abgede which was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from or its quality fell below that which it purported or was represented to possess, since it was represented to contain in each capsule 25 international units of vitamin B_1, equivalent to 45 Sherman units of vitamin B_1, whereas it contained in each capsule not more than 15 international units of vitamin B_1, equivalent to not more than 27 Sherman units of vitamin B_1.

It was alleged to be misbranded in that the statement, "Each Capsule Contains Not Less Than * * * Vitamin B_1—45 Sherman (25 Int.) units," borne on the boxes containing the article, was false and misleading since it contained not more than 15 international units of vitamin B_1, equivalent to not more than 27 Sherman units of vitamin B_1. It was alleged to be misbranded further in that the statement "Vitamins A B_1 G D," borne on the boxes, was misleading since it represented that the article contained therapeutic amounts of vitamins B_1 and G, whereas the article, when taken in the maximum dosage recommended and suggested, namely, 2 capsules per day, would supply not more than $\frac{1}{10}$ of the average therapeutic dose of vitamin B_1, and not more than $\frac{1}{40}$ of the amount of vitamin G required daily by an adult, which amounts of vitamins B_1 and G would be inconsequential for therapeutic purposes.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods reported in food notices of judgment.

On September 29, 1941, the defendant entered a plea of not guilty. On April 15, 1943, the case having come on before the court on a stipulation of facts and briefs submitted by the counsel for the defendant and the Government, the defendant was adjudged guilty and fined $200 on the 2 counts involving violation of the provisions of the law applicable to drugs, $100 of which, however, was suspended, and not guilty on the counts charging violation of the provisions applicable to foods. In announcing his decision, the court delivered the following memorandum opinion:

JENNEY, *District Judge:* "This is a criminal prosecution by the United States against Harold Hain, trading as the Hain Pure Food Company, for the violation of the Federal Food, Drug, and Cosmetic Act of 1938 (52 Statutes at Large 1040).

"The case is before the court under a stipulation of facts.

"In essence, the facts are as follows:

"The Defendant purchased a quantity of vitamin capsules from the International Vitamin Corporation of New York, which company manufactured, packaged, and labeled them. These were shipped to the defendant at his place of business in Los Angeles, in April 1939. Later, in June 1940, defendant obtained a guarantee from the International Vitamin Corporation assuring compliance with the Federal Food, Drug, and Cosmetic Act of any vitamin products they might sell to the defendant.

"In October 1940, defendant sold and shipped a quantity of these vitamin capsules in interstate commerce.

"In November 1940, a sample was taken from this shipment, which was tested and analyzed by an agent of the Food and Drug Administration. The vitamin potency, in respect to vitamin B_1, was found to be substantially below that represented on the labels of the boxes containing the capsules.

"The defendant did not alter the contents of the vitamin capsules, the contents of the boxes, nor the labels on the boxes.

"The information charges defendant with the violation of the Federal Food, Drug and Cosmetic Act of 1938 (Hereafter called, the Act), in four counts.

"The first count charges that the defendant delivered into interstate commerce an *adulterated food* in violation of the act.

"The third count charges that the defendant *misbranded* a *food* in violation of the act.

"The second count charges that the defendant delivered into interstate commerce an *adulterated drug* in violation of the Act.

"The fourth count charges that the defendant *misbranded* a *drug* in violation of the Act.

"These will be discussed in the order just stated.

"The apparent reason for drafting the information in four counts, and thereby presenting duplicate charges against the defendant—one based on a violation of the Act in respect to food, and the other in respect to drugs—is that there is a question as to whether concentrated vitamins in capsules are to be considered as a food or as a drug.

"The commercial use of concentrated vitamins in the fields of medicine and dietetics is a comparatively recent innovation. Experts in these fields disagree as to the category in which such vitamins are to be classed. However, it is not necessary for us to go into the subject extensively. Our inquiry is limited to the question of how vitamins should be classified solely in applying the provisions of the Act. In doing so, our first inquiry directs us to the definitions in the Act itself.

"In *21 U. S. C. A. 321 (g)*, it is stated: 'For the purposes of this chapter the term 'Drug' means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the U. S., *or* official National Formulary, . . .'

"The following vitamins are so recognized and listed in the Pharmacopoeia of the United States, 12th Revision, 1943: Vitamins A, B_1, C, D, D_2, D_3, and G.

"It is seen, therefore, that vitamins fall within the definition of 'drugs' insofar as the application of the Act is concerned. It is therefore immaterial in the determination of the case at bar how they are classified for other purposes.

"This interpretation is supported by the case of *United States v. Frank*, 189 Fed. 195, (1911). Here the court in interpreting a section similar to ours in the 1906 Food and Drug Act states at page 199: 'Section 6 of the Act of 1906 provides: "That the term 'drug' as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of diseases of either man or other animals . . ." These are mere terms of description. If the Pharmacopoeia or National Formulary says something is a drug, it is a drug under the meaning of the Act. . . .'

"The classification of vitamins as 'drugs' is logical in the light of analogous cases. This is well exemplified by the case of *Goodwin v. United States* (C. C. A., 6th Circuit) 2 Fed. (2nd) 200, where the court held that mineral water transported, not being in its original state, and processes of separation of the constituent drug elements being carried to the extent that the commercial water can no longer be used as a beverage, but only in small quantities as a drug, it is to be classified as a 'drug', and not a 'food', within the Food and Drug Act.

"We shall therefore deem concentrated vitamins as 'drugs' in the application of the Act before us.

"Since these vitamin products are 'drugs', count one and count three of the information are unsupported by the facts.

"Therefore, defendant is found not guilty as to counts one and three of the information.

"The allegations of violations of the Act in counts two and four, respectively, are concerned with the unlawful shipping of adulterated drugs in interstate commerce, and with the unlawful shipping of misbranded drugs in interstate commerce.

"In order that the prosecution may make out a prima facie case it is only necessary to show that defendant violated the express requirements of the Act. Good faith does not enter into the matter.

"*Strong, Cobb and Co.* v. *United States*, 103 Fed. (2d) 671. Here it was held that in a prosecution for shipment in interstate commerce of adulterated cold tablets in violation of the Federal Food, Drug and Cosmetic Act, *intent of defendant was not material*, since statute requires specific statements as to content of acetanilid compound.

"In *'Law of Foods, Drugs, and Cosmetics'* by Toulman, 1942 Edition, it is stated on page 75,: 'By the terms of the 1938 Act, good faith is a defence in criminal prosecution, when the charge is the *receiving* of adulterated or misbranded goods in interstate commerce. The good faith exemption does not apply when the charge is the *shipping* of misbranded or adulterated goods in interstate commerce. Therefore, intent, or something very like intent, must be proved by the government to secure a conviction when there is instituted a criminal prosecution for the receiving of adulterated or misbranded goods in interstate commerce. By implication, the new law *does not require intent to be proved* in cases where

there is instituted a criminal prosecution for the *shipping* of adulterated or misbranded goods in interstate commerce.'

"The sections of the Food and Drug Act involved here are:

"21 U. S. C. 331 (a), which states: 'The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.'

"21 U. S. C. 351 (c), which states: 'A drug or device shall be deemed to be adulterated if it is not subject to the provisions of paragraph (b) of this section and its strength differs from or its purity or quality falls below, that which it purports or is represented to possess.'

"21 U. S. C. 352 (a), states: 'A drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular.'

"It is readily seen that these statutes cover the stipulated facts in our case, and it is therefore unnecessary to repeat them.

"Therefore, a prima facie case has been made out by the Government against the defendant on both counts.

"However, the Act permits a defense to prosecution thereunder if a valid 'guaranty' has been obtained.

"This is set forth in 21 U. S. C. 333 (c), which states, 'No person shall be subject to the penalties of subscrion (a) of this section (2) for having violated section 331 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 221 (a),that such article is not adulterated or misbranded, within the meaning of this chapter, designating this chapter, or to the effect, in case of an alleged violation of section 331 (d), that such article is not an article which may not, under the provisions of section 344 or 355, be introduced into interstate commerce; . . .'

"In our case a purported guaranty was obtained fourteen months after acquiring the product.

"It is within the promise of the court to determine the legal meaning of documents.

"In *United States v. Glaser, etc.* (C. C. A. 7) 224 Fed. 84, it was held that the question of whether or not a given instrument in writing is a guaranty is a question of law, to be decided by the court.

"Therefore, the question as to whether this guaranty is valid, as being within the foregoing section and therefore exempting the defendant from liability is a question of law for the court to determine from the document.

"The object of this portion of the Act is to shift criminal responsibility rather than to absolve all parties therefrom. The reason for this is that the primary purpose of the Act is the protection of the public. It is only secondarily concerned with the question of the identity of the person who is to bear the brunt of the burden—i. e. between the manufacturer and the retailer—so long as there is positive responsibility in some party. This interpretation is supported by *Steinhardt Bros. and Co. v. United States* (C. C. A. 2nd). 191 Federal 798., *United States v. Antikammia Co.*, 231 U. S. 654.

"In *United States* v. *Mayfield*, et al., 177 Fed. 765, the court in construing the counterpart of our section in the 1906 Food and Drug Act, states: "The ninth section provides that no dealer shall be prosecuted under the provisions of the Act, when he can establish a guaranty, signed by the manufacturer from whom he purchased such articles, to the effect that the same article is not adulterated or misbranded within the meaning of the act; in which case, the manufacturer shall be amenable to the prosecutions, fines, and other penalties, which would otherwise attach to the dealer. The purpose of Congress was to place liability for the violation of the law upon some one in each instance. Primarily the liability is on the dealer who introduces the article into interstate commerce. The liability can be shifted from the dealer only by imposing the same liability upon the manufacturer. This can be done only by virtue of the manufacturer's guaranty to the dealer. If, for any reason, the guaranty is insufficient to impose liability upon the manufacturer, it remains where it primarily rested—upon the dealer. To have the effect of releasing the dealer from liability for the violation of the act, complained of in this prosecution, the guaranty must be of a character to impose liability for the same violation upon the manufacturer, if he were substituted for these defendants in this case; otherwise, both parties would escape liability, and the purpose expressed by Congress would be de-

feated. The act says that the manufacturer who signs the guaranty shall be subject to the same prosecution and penalties as the dealer. If a conviction could not be sustained against the manufacturer upon its guaranty, if substituted for the defendants in this case, then the taking of the guaranty by defendants would be no defense to their violation of the law in reference to the shipment in question, though they had no knowledge that it was adulterated or misbranded.'

"Therefore, in order for the defendant to be absolved of liability he must comply clearly with the Act.

"Here, Exhibit 'A' is claimed by defendant to be such a guaranty.

"The guaranty states that the International Vitamin Corporation guarantees that no food, drug, etc., 'now or hereafter' made for defendant will 'at the time of such shipment' be adulterated or misbranded within the meaning of the Act. Further on, it states that, 'This guaranty shall be a continuing guaranty . . .'

"This guaranty was given after the goods in question here were sold and delivered to the defendant.

"In order for the guaranty to be valid as a defense, it must refer to the specific goods and the specific sale in question.

"As stated in United States v. Mayfield (supra), 'In order for the manufacturer's guaranty to be effective to impose any liability upon him for any violation of law as to the article, which is the basis of this prosecution, the guaranty must relate to the identical article introduced into interstate commerce by the defendants as dealers. Otherwise the answer of the manufacturer to the prosecution would be that he had never guaranteed the article shipped by the dealer, and the answer would be complete.'

"This is clearly not the case in this guaranty. The language is susceptible of only one interpretation—that the guaranty was to be a 'continuing guaranty,' effective only from the date given, on into the future. Its meaning clearly does not include a guaranty of any sales made in the past.

"The apparent postscript on the document is claimed to have a retroactive effect, and to throw the guaranty within the purview of the exemption section.

"The postscript reads, 'The above guarantee applies to all merchandise shipped by us against your contracts.' It is then signed by an unidentified 'F. Satz.'

"This language may possibly be ambiguous. However, construed in the light of the guarantee, it becomes apparent that it is capable of only one meaning. That is, that the guaranty is a continuing guarantee.

"However, assuming arguendo, that it meant all the defendant claims it means, it still would not help him. Two interpretations may be made of this postscript. One is that Satz is attempting to interpret the meaning of the guaranty; the other that Satz is attempting to supplement the legal liability of the corporation. The first view is of no effect here, because that is a question of law for the court to determine. The second view has no effect because there is no showing that Satz had authority to bind the corporation, or even that he was attempting to bind the corporation. Further, if he signed it with his personal backing, it is fatal because, as stated in Regulation (g) under 21 U. S. C. 303 (c), 'A guarantee or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.' This was not done here.

"Therefore, under any of the foregoing interpretations it is seen that there is no guaranty which would cover the goods in question.

"Because of the foregoing, this guaranty fails in its validity for the purpose of exempting the defendant from prosecution, and in effect is as though no guaranty at all were given. This eliminates any defense defendant might have in this respect.

"Defendant is found guilty of count two and count four as charged in the information.

"*The penalties under this act are:* (21 U. S. C. A. 333 (a), (b))

"(1) Imprisonment for not more than one year, a fine of not more than $1,000, or both, as for a misdemeanor.

"(2) If the accused has already been convicted once, under that statute, the penalty is imprisonment for not more than 3 years, and a fine of not more than $10,000, or both.

"(3) If the violation is with intent to defraud and mislead, the penalty is the same as if the accused had already been once convicted."